ALKA-SELTZER PLUS MAXIMUM STRENGTH SEVERE SINUS, ALLERGY AND COUGH-
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled
Bayer HealthCare LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka-Seltzer Plus® Maximum Strength Severe Sinus, Allergy & Cough Liquid Gels

Drug Facts

Active ingredients (in each capsule)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestan

Uses

Uses

· temporarily relieves these symptoms due to hay fever or other upper
respiratory allergies:
· runny nose · sneezing
· itching of the nose or throat · itchy, watery eyes
· temporarily relieves these symptoms due to a cold:
· nasal congestion · sinus congestion and pressure
· headache · minor aches and pains · cough
· temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
· more than 4,000 mg of acetaminophen in 24 hours
· with other drugs containing acetaminophen
· 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin or severe
allergic reactions. Symptoms may include:
· skin reddening · blisters · rash · hives

· facial swelling · asthma (wheezing) · shock

If a skin or general allergic reaction occurs, stop use and seek medical help right away.

Do not use to sedate children.

Do not use

● with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

● if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

● if you have ever had an allergic reaction to this product or any of its ingredients

● in children under 12 years of age

Ask a doctor before use if you have

● liver disease ● heart disease ● high blood pressure

● thyroid disease ● diabetes ● glaucoma

● cough with excessive phlegm (mucus)

● a breathing problem such as emphysema or chronic bronchitis

● difficulty in urination due to enlargement of the prostate gland

● persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

● taking the blood thinning drug warfarin

● taking sedatives or tranquilizers

When using this product

● do not exceed recommended dosage

● may cause marked drowsiness

● avoid alcoholic drinks

● alcohol, sedatives, and tranquilizers may increase drowsiness

● be careful when driving a motor vehicle or operating machinery

● excitability may occur, especially in children

Stop use and ask a doctor if

· pain, cough, or nasal congestion gets worse or lasts more than 7 days

· fever gets worse or lasts more than 3 days

· redness or swelling is present

· new symptoms occur

· cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

· nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Directions

· do not take more than the recommended dose

· adults and children 12 years and over: take 2 capsules with water every 4 hours. Do not exceed 10 capsules in 24 hours or as directed by a doctor.

· children under 12 years: do not use

Other information

Other information

● store at room temperature. Avoid excessive heat above 40°C (104°F)

Inactive ingredients D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)


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MAXIMUM STRENGTH
Severe Sinus
Allergy & Cough
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MAXIMUM STRENGTH
Severe Sinus
Allergy & Cough
ACETAMINOPHEN / Pain Reliever-Fever Reducer
Dextromethorphan HBr / Cough Suppressant
Doxylamine succinate / Antihistamine
Phenylephrine HCl / Nasal Decongestant
Sinus Congestion & Pressure
Headache & Pain
Runny Nose & Sneezing
Itchy, Watery Eyes
Cough
BAYER
20 LIQUID GELS (Liquid Filled Capsules)
3486
3486

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Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0280-1620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-1620-20	2 in 1 CARTON	06/26/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/26/2017	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2019 Bayer HealthCare LLC.